

U.S. Department of Transportation

Research and Special Programs Administration

FEB 1 9 2003

Ms. Ruth O'Donnell CHMM Safety Specialist The Blood Center 638 North 18th Street Milwaukee, WI 53201-2178

Dear Ms. O'Donnell:

Ref No. 02-0325

400 Seventh St., S.W.

Washington, D.C. 20590

This is in response to your December 4, 2002 letter, requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to regulated medical waste. Specifically, you question if the Materials of Trade (MOTS) exception as revised in the Final Rule, Revision to Standards for Infectious Substances, under Docket No. HM-226, applies to regulated medical waste transported by private motor carriers.

This Final Rule expands the MOTS exceptions currently permitted under § 173.6 of the HMR for hazardous materials carried by private motor carriers engaged in a principal business other than transportation. The MOTS exceptions apply to Division 6.2 material, other than a Risk Group 4 material, that is a diagnostic specimen, biological product, or regulated medical waste. The material must meet the definition of a diagnostic specimen, biological product, or regulated medical waste found in § 173.134. The material must be contained in a combination packaging. For liquids, the inner packaging must be leak tight, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging must be constructed of a rigid material resistant to punctures and leaks. For all Division 6.2 materials, the outer packaging must be a strong, tight packaging securely closed and secured against movement. For a regulated medical waste, a combination packaging must consist of one or more inner packaging having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon), and an outer packaging having a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons).

I hope this information is helpful. If we can be of further assistance, do not hesitate to contact us.

Sincerely,

Delmer F. Billings

Chief, Standards Development

Office of Hazardous Materials Standards



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December 4, 2002

Mr. Edward T. Mazzullo Director, Office of Hazardous Materials Standards U.S. DOT/RSPA (DHM-10) 400 7th St., S.W. Washington, DC 20590-0001

Dear Mr. Mazzullo,

This letter serves as a request for a written clarification on the applicability of the Material of Trade Exception as found in 49 CFR 173.6 to regulated medical waste in light of the recent revision to standards for infectious substances (HM-226).

As a blood center, we have satellite sites across the state in which blood is collected from donors. In the course of collecting blood regulated medical waste is generated. On a daily basis blood products are transported via private motor carrier back to our headquarter facility for testing, processing and distribution. While the blood products are excepted from regulation under 49 CFR 173.134(b)(5), the regulated medical waste is not.

If the regulated medical waste is in compliance with packaging requirements, quantity limitations and operator requirements as stated in 49 CFR 173.6, would the Material of Trade exception apply to regulated medical waste transported via private motor vehicles? These private vehicles directly support our blood banking business.

Thank you in advance for your interpretation. If you have any questions, or require clarification, please contact me at 414-937-6289.

Sincerely,

Ruth O'Donnell CHMM

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Safety Specialist

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